UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

January 31, 2002

MEMORANDUM:

Subject: Efficacy Review EPA 71661-R Surfacine All-Purpose Cleaner
DP Barcode 279078
Case No. 070100

From: Nancy Whyte, Microbiologist NOW
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward/Renae Whitaker
Regulatory Management Branch II
Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader Emily Mitchell 2/5/02
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Intelligent Biocide LLC
One Industrial Way
Tyngsboro, MA 01879

Formulation Label:

Active Ingredient(s)	**% by wt.**
Silver..(from silver nitrate)	0.0095%
Poly (hexamethylenebiguanide) hydrochloride	0.560 %
Inert ingredients	99.4305%
Total	100 0000%

I. Background:

The consultant for the registrant has submitted a document (MRID No. 455283-01)

to address the Agency's comments concerning a deficiency in the efficacy testing which was submitted in the Spring of 2001. The efficacy review DP Barcode 273267 is attached. Most of the data in the document consists of handwritten notes describing preparation of a solution is not identified. There is also a statement on page 5 attesting to the age of the product. This is also attached.

II. Findings:

1. The handwritten pages do not identify the solution being prepared and do not have any apparent value to support the age or the batches of the solutions used in the testing conducted by the laboratory to confirm the effectiveness of the product against the organisms tested. The date of 12/13/00 appears on 9 and 12 of the document which would seem to indicate that this solution was prepared on that date.

2. The statement on page 5 of this same document lists the organisms tested, the name of the product, the batch numbers of the product used in the testing, and the date the efficacy study was begun. This data are consistent with the material presented in the original study submitted to the Agency in 2001 and summarized in the previous efficacy review.

III. Comments and Recommendations:

1. Although the data submitted did not originate from the laboratory which conducted the efficacy testing, the statement certifies that there was at least one batch of product which was 61 days old. The Product Manager who handles this product has stated that this is acceptable for verification.

2. Deficiencies in the label noted by the Agency were not addressed in this submission.

ATTACHMENT I

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

May 18, 2001

MEMORANDUM:

Subject: Efficacy Review EPA 71661-R Surfacine All-Purpose Cleaner
DP Barcode 273267
Case No. 070100

From: Nancy Whyte, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward/Renae Whitaker
Regulatory Management Branch II
Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader
Efficacy Evaluation Team
Product Science Branch
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Total	100 0000%

I. Background:

The registrant has submitted a registration application for what is proposed as new uses for this combination of active ingredients. Silver, in the form of silver nitrate, is reacted with PHMB and [redacted] forming an insoluble complex of stable PHMB/silver microparticles. The product, also containing a non-ionic detergent for cleaning, is said to kill microorganisms on contact with hard, non-porous, non-food surfaces.. Future registration applications for other products with residual effectiveness claims are expected. Submitted for review with this application were two documents (MRIDs No. 453288-10 and -11) containing efficacy studies to support public health label claims.

II. Use Directions:

The product is packaged as a ready-to-use spray for general cleaning, sanitization, and disinfection on non-food contact surfaces. For cleaning, soiled surfaces should be sprayed at a distance of 6-10 inches and wiped with a dry paper towel or lint-free cloth. To prevent mold and mildew, surfaces should be pre-cleaned if heavily soiled, then sprayed until thoroughly wet and allowed to remain wet for 30 seconds before wiping. (Directions for sanitization are also included, but product has not been tested for effectiveness as a sanitizer) To use as a disinfectant, the spray must be allowed to stand on thoroughly wet treated surfaces for 10 minutes before wiping.

III. Agency Standards for Registration:

Agency standards are found in DIS-TSS-1 which specifies the use of the Association of Official Analytical Chemists (AOAC) Germicidal Spray Products Test. Sixty carriers must be tested with each of three samples representing 3 batches, one of which must be at least 60 days old, against *Salmonella choleraesuis* ATCC 10708 and *Staphylococcus aureus* ATCC 6538. To support use in hospital or medical environments, the product must also be tested against *Pseudomonas aeruginosa* ATCC 15442, using the same procedure as listed above. (180 carriers per sample, a total of 540 carriers) To support the claim of the product as a disinfectant, it must kill all organisms on 59 out of 60 carriers tested for each organism, using 3 batches of product to provide effectiveness at the 95% confidence level. Supplemental claims, such as for mold and mildew control, are set forth in DIS-TSS-6. The inoculum must provide a concentration of at least 106 conidia per carrier. Ten carriers on each of 2 samples from 2 different product batches must be tested, and all test organisms must be killed.

IV. Summary of Submitted Study:

The efficacy tests for this product were conducted by ViroMed Biosafety Laboratories in Minneapolis, MN in January and February 2000. The test was conducted using the AOAC Germicidal Spray Method, *Official Methods of Analysis of the AOAC,15th ed,,Chap 6, 961.02* Both signed Quality Assurance and Good Laboratory Practice Statements were included in the study documents submitted to the Agency. The organisms specified by the Agency, *Salmonella choleraesuis,* 10708, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442 and *Trichophyton mentagrophytes* ATCC 9533, .to test the product effectiveness

Bacterial organisms were prepared for testing by subculturing a stock culture for four successive days. Transfers were streaked for isolation to demonstrate typical colonial morphology typical of the test organism. Prior to testing, 48-54 hour cultures were mixed, allowed to settle, and an organic soil load of 5% fetal bovine serum was added to the tubes.

Sterile glass slides were used as carriers and were inoculated with 0.01 ml. of the test organism using an calibrated pipettor. The inoculum was spread evenly over the entire surface and allowed to dry in a sterile covered petri dish by incubation at 37° C for 30–40 minutes. Three batches of the product, designated 5006-23-1, 5006-23-2, and 5006-23-3, were supplied ready to use to the lab by the registrant.. There was no reference in the study to the relative age of the product batches or whether one of the batches was at least 60 days old. When slides were dried, they were uniformly sprayed individually at staggered intervals with the test substance for 2-3 seconds at a distance of 6-8 inches, and allowed to remain in contact with the spray material for 10 minutes. After treatment, the liquid was drained from the slides, placed in 20 ml aliquots of neutralization broth, and incubated for 48 +/- 4 hours at 35-37° C. Following incubation, the subcultures were examined for presence or absence of visible growth. There was no growth in each of 60 of 60 carriers (total of the three bacterial organisms.

The same procedure used for the bacterial cultures was followed for *Trichophyton* with the exception of the preparation of the conidial suspension and the incubation time of 12 days for the initial transfer from the stock culture. Only ten carriers of the organism were used to test the effectiveness of each of the three samples. The same lots of the product 5006-23-1, 5006-2 and 5006-23-3 were used in testing. An organic soil load of FBS was used in the same manner as for the bacterial cultures. Treated slides were dried for 30 minutes at 36° C and incubated for 10 days at 25-30° C. Those showing visible growth were inoculated onto fungal agar for confirmation of test organism. There was no growth in any of the carriers (total 30 carriers)

V. Labeling:

2. The words "to sanitize surfaces" listed in the use directions must be removed. The product has not been tested for effectiveness as a non-food contact sanitizer. Remove all claims "Kills 99.99% of germs" because this is a sanitizing claim.

3. The uses for this product on kitchen countertops and high chairs are not allowed and .must be removed. These are considered food-contact surfaces. The use for refrigerators must be modified by stating "exterior of refrigerator surfaces".

4. The term "New" can only be used on a product label for a 6-month period, and then it must be removed.

4. Change the wording "Athletes' Foot Fungus" to read "Trichophyton mentagrophytes which causes athletes' food fungus".

5. Remove "Disinfects on contact". The product requires a 10-minute contact time for for disinfection.

VI. Comments and Recommendations:

1 The efficacy studies state that three separate batches of the product were used in testing, but it was not evident from the laboratory report that one of the batches was at least 60 days old, as is required by the standard testing procedure.

2. The product has demonstrated effectiveness against *Salmonella choleraesuis* ATCC

10708, *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15442, and *Trichophyton mentagrophyes* ATCC 9533 when exposed to the product for 10 minutes in the presence of 5% organic soil.

3. Label claims for use of this product as a sanitizer and for use in the kitchen on counter tops and high-chairs are not allowed and must be removed from the label. The use for refrigerators must be modified.

ATTACHMENT II

ABSTRACT

This study is an addendum to the study titled, "AOAC Germicidal Spray Method; Test Organism: *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis,* MRID #45328811. This addendum attempts to support the claim that th product batches tested on *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella choleraesuis* in MRID #45328811 were at least 60 days old, as required by EPA testing guidelines.

Notebook entries documenting the preparation of Surfacine Cleaner Disinfectant batches tested in MRID # 45328811 were prepared on December 11, 1999. As indicated in MRID #45328811, the "Experimental Start Date" was February 11, 2000. Therefore, product batches tested against *Pseudomonas aeruginosa, Staphylococcus aureus,* and *Salmonella choleraesuis* in MRID #45328811 were 61 days old.

SUMMARY

Test Substance Name:.....Surfacine Cleaner Disinfectant
Batch No......5006–23-1, 5006-23-2, 5006-23-3
Date Product Batch Prepared:.....December 13, 1999
Experimental Start Date:.....February 11, 2000.
Age of Product Batch:.....61 days